

articles contained statements which represented and suggested that the sodium phosphate was an adequate and effective treatment for gas, heartburn, and other distress, and that the sodium sulfate would effect a direct liver reaction to remove stagnant bile, which statements were false and misleading since the sodium phosphate was not an adequate and effective treatment for the conditions stated and the sodium sulfate would not effect a direct liver reaction to remove stagnant bile; and, Section 502 (f) (2), the labels of the articles failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe methods or duration of administration, in such manner and form, as are necessary for the protection of users since their labeling did not bear warnings against use in case of nausea, vomiting, abdominal pain, or other symptom of appendicitis, nor against frequent or continued use which may cause dependency upon laxatives to move the bowels. The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

Calcium phosphate—drug in powder form (in bulk container and as repacked). Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purpose for which the article was intended. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

Drug in powder form repacked from unlabeled container into retail-sized containers and labeled "ABCO." Misbranding, Section 502 (a), the label statements "for revulsive hand, foot and abdominal hot applications. Neck, spine and congestive areas need ABCO sprinkled on a cold compress" were false and misleading since the article was not effective for the purposes stated and implied. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: June 17, 1953. L. W. Andrus, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the drugs be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare, and that the above-mentioned booklets, mimeographed sheets, and leaflets be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4085. Misbranding of pentobarbital sodium capsules and sulfathiazole tablets and conspiracy to violate the laws of the United States. U. S. v. Harry W. Wilson (Wilson Drug Co.), and Seth R. Medley. Pleas of guilty. Defendant Wilson fined \$640 and sentenced to 6 months in jail; jail sentence suspended and defendant placed on probation for 1 year. Defendant Medley fined \$114. (F. D. C. No. 33715. Sample Nos. 85336-K, 85345-K, 85346-K, 85350-K, 85351-K, 19318-L, 19319-L, 19332-L, 19340-L, 19348-L, 19356-L, 19364-L, 19367-L, 19368-L.)

INFORMATION FILED: December 16, 1952, Western District of Wisconsin, against Harry W. Wilson, trading as the Wilson Drug Co., Spooner, Wis., and Seth R. Medley, a physician.

ALLEGED VIOLATION: On or about November 6 and December 1 and 18, 1950, and January 5 and 24, March 4, 20, and 30, April 12, and May 2, 1951, while a number of *pentobarbital sodium capsules* and *sulfathiazole tablets* were

*See also Nos. 4083, 4084.

being held for sale after shipment in interstate commerce, Defendant Wilson repacked and dispensed to one, Thomas H. Kingsley, various quantities of such drugs without a prescription therefor, which acts resulted in the repackaged drugs being misbranded in violation of Section 301 (k).

The information charged further, in counts 2, 3, 6, 7, and 14, that as a part of the acts of repacking and dispensing the *pentobarbital sodium capsules* and *sulfathiazole tablets* on December 1 and 18, 1950, and as a part of the acts of repacking and dispensing the *sulfathiazole tablets* on May 2, 1951, Defendant Wilson filled out, on or about December 1, 1950, and May 2, 1951, paper forms the size and style of a physician's prescription form, commonly and usually containing directions to a pharmacist for the purpose of dispensing drugs; that after such forms had been filled out and as a part of the acts of repacking and dispensing, Defendant Medley, a physician, affixed his signature to such paper forms; that Thomas H. Kingsley, whose name appeared on the paper forms, was not a patient of Defendant Medley at any time; that after Defendant Medley had signed the paper forms, Defendant Wilson placed the paper forms in the prescription files of the Wilson Drug Co.; and that the act by Defendant Medley of signing the paper forms was an act which aided and abetted defendant Wilson in his violation of Section 301 (k).

The information alleged further, in count 15, that Defendants Wilson and Medley combined, conspired, and agreed together and with each other to violate Section 301 (k); that it was a part of the conspiracy that the defendants would dispense and cause to be dispensed, without labeling bearing adequate directions for use, *pentobarbital sodium capsules* and *sulfathiazole tablets* which had been shipped in interstate commerce into the State of Wisconsin and were being held for sale after such shipment; and that the acts of Defendant Wilson in repacking and dispensing the *pentobarbital sodium capsules* and the *sulfathiazole tablets* involved in counts 2, 3, 6, 7, and 14, and the act of Defendant Medley in aiding and abetting Defendant Wilson in the violation of Section 301 (k), as described above, were done in pursuance of the conspiracy and to effect the objects thereof.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the label of the repackaged *sulfathiazole tablets* failed to bear the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged *sulfathiazole tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 5, 1953. The defendants having entered pleas of guilty, the court fined Defendant Wilson \$640 and Defendant Medley \$114. In addition, the court imposed a sentence of 6 months in jail against Defendant Wilson, but suspended the sentence, and placed this defendant on probation for 1 year.